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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
YAO, LEI	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 01/27/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/809,144	COSTA ET AL.	
	Examiner	Art Unit	
	Lei Yao, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 March 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-49* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-49* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-3 in part, 7-10 in part, 4-6, drawn to a method of inhibition proliferation of a tumor cell comprising the step of inhibiting FoxM1B activity in the tumor cells, wherein FoxM1B activity is inhibited by tyrphostin, classified in class 435, subclass 4.

II. Claims 1-3 in part, 7-10 in part, 11, drawn to a method of inhibition proliferation of a tumor cell comprising the step of inhibiting FoxM1B activity in the tumor cells, wherein FoxM1B activity is inhibited by contacting the cell with a peptide, classified in class 435, subclass 7.1.

III. Claims 1-3 in part, 7-10 in part, 12, drawn to a method of inhibition proliferation of a tumor cell comprising the step of inhibiting FoxM1B activity in the tumor cells, wherein FoxM1B activity is inhibited by a Cdk1 inhibitor, classified in class 435, subclass 4.

IV. Claims 1-3 in part, 7-10 in part, 13, drawn to a method of inhibition proliferation of a tumor cell comprising the step of inhibiting FoxM1B activity in the tumor cells, wherein FoxM1B activity is inhibited by interfering with the ability of FoxM1B to interact with P300/CBP, classified in class 435, subclass 7.1.

V. Claims 1-3 in part, 7-10 in part, 14, drawn to a method of inhibition proliferation of a tumor cell comprising the step of inhibiting FoxM1B activity in the tumor cells, wherein FoxM1B activity is inhibited by disrupting protein activity or interactions among protein comprising the P13K/PDK1 pathway, classified in class 435 subclass 4 and 7.23.

VI. Claims 1-3 in part, 7-10 in part, 15, drawn to a method of inhibition proliferation of a tumor cell comprising the step of inhibiting FoxM1B activity in the tumor cells, wherein FoxM1B activity is inhibited by disrupting protein activity or interactions among protein comprising the Ras/MAPK pathway, classified in class 435, subclass 4, and 7.1.

VII. Claims 1-3 in part, 7-10 in part, 16, drawn to a method of inhibition proliferation of a tumor cell comprising the step of inhibiting FoxM1B activity in the tumor cells, wherein FoxM1B activity is inhibited by contacting a tumor cell with an antisense oligonucleotide, classified in class 536, subclass 24.1.

VIII. Claim 17, drawn to a pharmaceutical composition comprising a peptide having an amino acid sequence as set forth in SEQ ID NO: 10 or 11, or 12, classified in class 530, subclass 300

IX. Claims 18, drawn to a method of inhibiting tumor growth in an animal comprising administering to the animal a pharmaceutical composition, classified in class 514, subclass 2.

X. Claims 19-20 in part, 24-27 in part, 21-23, drawn to a method of inhibiting tumor growth in an animal comprising administering to the animal, a therapeutically effective amount of a compound that inhibits Fox M1B activity, wherein the compound is tyrphostin, classified in class 514, subclass 1 and class 424, subclass 7.23.

XI. Claims 19-20 in part, 24-27 in part, 28, drawn to a method of inhibiting tumor growth in an animal comprising administering tot eh animal, a therapeutically effective amount of a compound that inhibits Fox M1B activity, wherein FoxM1B activity is inhibited by a Cdk1 inhibitor, classified in class 514, subclass 1 and class 424, subclass 7.23.

XII. Claims 19-20 in part, 24-27 in part, 29, drawn to a method of inhibiting tumor growth in an animal comprising administering tot eh animal, a therapeutically effective amount of a compound that inhibits Fox M1B activity, wherein FoxM1B activity is inhibited by interfering with the ability of FoxM1B to interact with P300/CBP, classified in class 514, subclass 1 and class 424, subclass 7.23.

XIII. Claims 19-20 in part, 24-27 in part, 30, drawn to a method of inhibiting tumor growth in an animal comprising administering tot eh animal, a therapeutically effective amount of a compound that inhibits Fox M1B activity, wherein FoxM1B activity is inhibited by

disrupting protein activity or interactions among protein comprising the P13K/PDK1, classified in class 514, subclass 1 and class 424, subclass 7.23.

XIV. Claims 19-20 in part, 24-27 in part, 31, drawn to a method of inhibiting tumor growth in an animal comprising administering tot eh animal, a therapeutically effective amount of a compound that inhibits Fox M1B activity, wherein FoxM1B activity is inhibited by disrupting protein activity or interactions among protein comprising the Ras/MAPK pathway, classified in class 514, subclass 1 and class 424, subclass 7.23.

XV. Claims 19-20 in part, 24-27 in part, 32-36, drawn to a method of inhibiting tumor growth in an animal comprising administering to an animal a therapeutically effective amount of a compound that inhibits Fox M1B activity, wherein FoxM1B activity is inhibited is inhibited by contacting a tumor cell with an antisense oligonucleotide, classified in class 514, subclass 44.

XVI. Claims 37, drawn to a method of identifying compounds that inhibits nuclear localization of FoxM1comprisign contacting a cells with a candidate compound, classified in classified in class 514, subclass 1 and class 424, subclass 7.23.

XVII. Claims 38, drawn to a method identifying compounds that inhibits nuclear localization of FoxM1b comprising contacting a transgenic mouse with a candidate compound, classified in class 800, subclass 3.

XVIII. Claims 39, drawn to identifying compounds that prevent tumor cell proliferation in an animal or human comprising contacting with a candidate compound a plurality of cells comprising a FoxM1B gene, in vitro, classified in class 435, subclass 4.

XIX. Claims 40 drawn to a method of identifying compounds that can inhibit tumor progression in an animal or human, comprising a assaying Fox1B localization, classified in class 435, subclass 4 and class 514, subclass 1.

XX. Claims 41 drawn to a method of identifying compounds that can inhibit tumor progression in an animal, comprising a assaying Fox1B activity in a cells, classified in class 514, subclass 1 and class 424, subclass 9.1 and 7.23.

XXI. Claims 42-46, drawn to a method of inhibiting tumor cell proliferation comprising delivering to a tumor cell an antisense oligonucleotide, classified in class 514, subclass 44.

XXII. Claims 47-49, drawn to a method of identifying compound that can inhibit FoxM1B transcriptional activity of transformation in tissue culture systems, classified in class 514, subclass 44.

Inventions are distinct each from the other because of the following reasons:

Inventions Group VIII and Group II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group II can be used to immunize an animal to produce an antibody, as opposed to being used to contact cell by inhibiting FoxM1B activity.

Searching the inventions of Groups VIII and II together would impose serious search burden. The inventions have a separate status in the art as shown by their different classifications. Moreover, in the instant case, the searches for the peptide and a method of using the peptide for inhibiting FoxM1b activity are not co-extensive. Prior art, which teaches the peptide would not necessarily be applicable to the method of using the peptide in inhibiting FoxM1b activity. Moreover, even if the peptide was known, the method a method of specifically using the peptide in may be novel and unobvious in view of the preamble or active steps.

Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).

The methods of Group I, III-VII, IX-XXII differ in the method objectives, method steps and parameters and in the reagents used. The instant specification does not disclose these methods would be used together. Each invention performs its function using a structurally and functionally divergent

material and having different method steps and method objective. The methodology and materials necessary for one group differ significantly from others.

The distinct method steps and materials used in each method have a separate status in the art as shown by their different classifications and require separate searches. Searching all the invention groups together or even two group together would impose serious search burden and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

Furthermore, if applicants elect invention group II or VIII, **further restriction** is required under 35 U.S.C. 121:

Elect one single polypeptide from the following: SEQ ID NO: 10, 11, or 12.

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to *different* products, restriction is deemed to be proper because these products constitute patentably distinct inventions for the following reasons. Each of SEQ ID NOs is a unique and separately patentable sequence, requiring a unique search of the prior art. Searching all of the sequences in a single patent application would constitute an undue search burden on the examiner and the USPTO's resources because of the non-coextensive nature of these searches.

In order to be fully responsive, if Applicant elect group II or VIII, one must elect one sequence form SEQ ID NO: 10, 11,12 even though the requirement is traversed. Applicant is advised that neither II, VIII nor SEQ ID NOs is species election requirement; rather, each of II and VIII, and SEQ ID NOs election is a restriction requirement.

Election of Species

This application contains claims directed to the following patentably distinct species of the claimed invention:

a. Malignant tumor cell or benign tumor cell
b. Epithelial cell of origin listed in claim 10, or 27
c. Viral vector listed in claim 35, or 45

In the event that applicant elects any invention I-XXII ,wherein the claims comprise inhibition of tumor growth, applicant is required under 35 U.S.C. 121 to elect **ONE single species listed in a) and b)** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. For example, malignant tumor cell from a) and breast from b).

In the event that applicant elects invention XV or XXI, applicant is required under 35 U.S.C. 121 to elect **ONE single virus vector species from c)** for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitation of the allowable product claim will be rejoined in accordance with the provisions of M.P.E.P. 821.04. Process claims that depend from or otherwise include all the limitation of the patentable product will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after allowance are governed by 37 C.F.R. 1.312.

In the event of a rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 C.F.R. 1.104. thus, to be allowable, the rejoined claims must meet the criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of In re Ochiai, In re Brouwer and 35 U.S.C. 103(b), 1184 O.G. 86 (March 26, 1996).

Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that process claims should be amended during prosecution either to maintain dependency on the product claims or otherwise include the limitation of the product claims. Failure to do so may result in a loss of the right to rejoinder.

Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See M.P.E.P. 804.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lei Yao, Ph.D. whose telephone number is 571-272-3112. The examiner can normally be reached on 8am-4.30pm Monday to Friday.

Any inquiry of a general nature, matching or file papers or relating to the status of this application or proceeding should be directed to Kim Downing for Art Unit 1642 whose telephone number is 571-272-0521

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lei Yao, Ph.D.
Examiner
Art Unit 1642

LY

JEFFREY SIEW
SUPERVISORY PATENT EXAMINER
1/19/06